ULTRADENT PRODUCTS, INC.

K063558

SPECIAL 510(K) PREMARKET SUMMARY

Peak™ SE

DEC

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for Peak™ SE.

Applicant's Name and Address:

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Telephone Number:	(801) 553-4491
Fax Number:	(801) 553-4609
Contact Person:	Diane Rogers, R/A Product Specialist
Date Summary Prepared	November 20, 2006

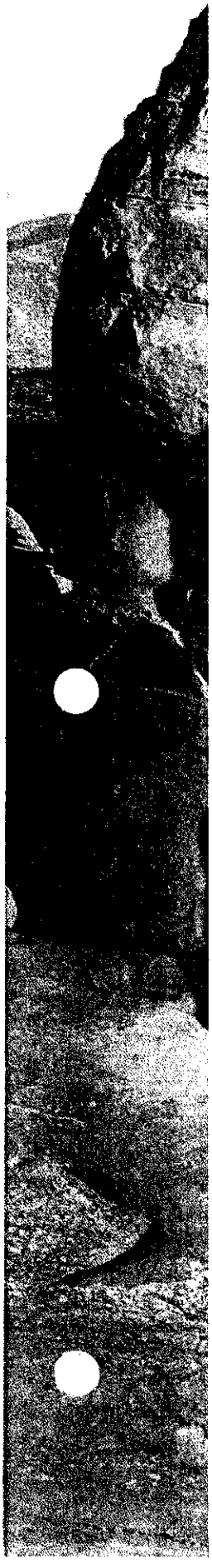
Name of the Device:

Trade name:	Peak™ SE
Common Name:	SE Resin Bonding System
Classification Name:	Resin Tooth Bonding Agent
Risk Class:	II, (21 CFR 872.3200)
Classification Product Code:	76KLE

Legally Marketed Predicate Devices to which Equivalence is Claimed:

PermaQuick™ SE Bonding System K032626
Manufactured and distributed by Ultradent Products, Inc.
505 West 10200 South, South Jordan, Utah 84095.

Clearfil SE Bond K990040
Manufactured and Distributed by Kuraray America Inc.
101 East 52nd Street, 26th Floor
New York, NY 10122



Device Description and Performance Characteristics:

Peak™ SE Bonding System is a syringe delivered self-etching primer component of the Peak™ Resin Bonding System.

Intended Use:

For use in most light-accessible bonding procedures in both the anterior and posterior. Peak™ SE is used with Peak™ Bond Adhesive for dentin, enamel porcelain and composite bonding.

Technological Characteristics:

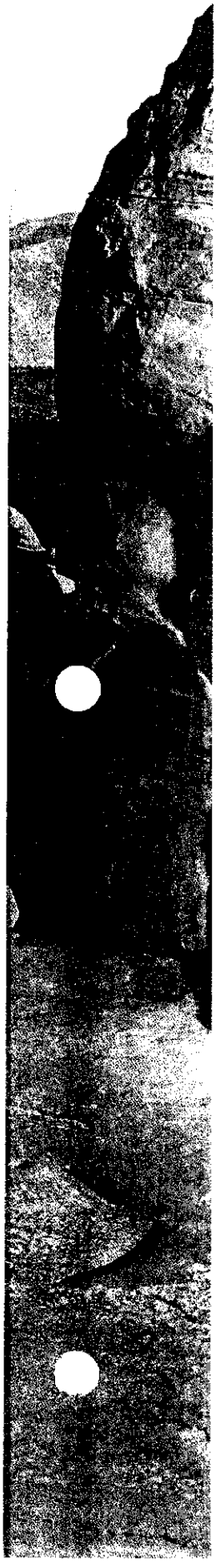
Peak™ SE is a syringe delivered self-etching primer component of the Peak™ Resin Bonding System. Our unique MixSyr delivery (syringe-in-syringe) ensures a fresh mix of chemistry for every procedure. Peak™ SE is to be used specifically with our syringe delivered, light cured bonding agent, Peak™ Bond. Peak™ SE is 7.5% filled and radiopaque. The system will cure with most high intensity lights including LEDs.

Brief Description of Testing Performed and Conclusion:

Peak™ SE was designed, tested and compared to its predicates, **PermaQuick™ SE**, Ultradent Products, Inc. and Clearfil SE, Kuraray Co. Ltd. in the following categories: Intended Use, Description, Biocompatibility and Safety, Properties, Ease of Use, Ingredients, Radiopacity, Shrinkage and Bond Strength. All of our testing concluded that Peak™ SE has met or exceeded our testing expectations.

Substantial Equivalence

In conclusion, Peak™ SE, that is to be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, Utah 84095, is substantially equivalent to our PermaQuick™ SE which has the same intended use, and are equally safe for the indications as described. Please feel free to contact me for further explanation and dialogue with respect to this product, as it is my understanding that the product is substantially equivalent to products



legally marketed for this indication. I can be reached for discussion at the number listed above and would appreciate the opportunity to further clarify as necessary.

Diane Rogers

Diane Rogers
Regulatory Affairs Product Specialist

November 20, 2006
Date

505 West 10200 South, South Jordan, Utah 84095, USA • 800.552.5512 • Fax: 801.572.0600 • www.ultradent.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diane Rogers
Regulatory Affairs Product Specialist
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

DEC 14 2006

Re: K063558
Trade/Device Name: Peak™ SE
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 21, 2006
Received: December 08, 2006

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

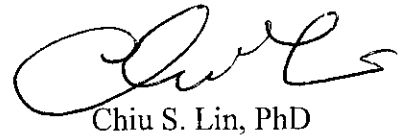
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063557

Device Name: Peak™ SE

Indications for Use:

Use for most bonding needs in restorative dentistry. Bonds chemical cure luting and chemical cure composites, namely PermaFlo DC. Peak SE does not require a separate etching step for quality adhesion. Peak SE is also conducive for bonding to:

- Dentin and enamel
- Porcelain
- Metal
- Composite

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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